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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,511	01/19/2001	Sean A. McCarthy	10147-65 (MPI2000-537OMNI	9759

570 7590 09/30/2002

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,511	MCCARTHY ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 12 and 26-34, drawn to an isolated nucleic acid, vectors thereof, host cells, and methods of recombinant expression of such, wherein the nucleic acid comprises SEQ ID NO:1 or 2, classified in class 435, subclass 69.1.

II. Claims 8-10 and 35-43, drawn to isolated polypeptides, classified in class 530, subclass 350.

III. Claims 11, 23 and 24, drawn to antibodies specific to said polypeptides, and a method of making the antibody, classified in class 530, subclass 387.9.

IV. Claims 11, 23 and 25, drawn to antibodies specific to said polypeptides, and a method of making the antibody, classified in class 530, subclass 387.9.

V. Claims 13 and 14, drawn to a method for detecting said polypeptide, classified in class 436, subclass 501.

VI. Claim 15, drawn to a kit comprising a compound binding to said polypeptide, classified in class 436, subclass 808.

VII. Claims 16-18, drawn to a method, and a kit for detecting said nucleic acid molecules, classified in class 435, subclass 6.

VIII. Claims 19, 20, and 22 drawn to a method for identifying a compound, classified in class 436, subclass 501.

IX. Claim 21, drawn to a method for modulating the activity of said polypeptide, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptides of Invention II by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecule and the polypeptide are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be

made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay of Invention VII.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The products of Invention I are distinct and unrelated from the antibody of Inventions III and IV because they are physically and functionally distinct chemical entities which share neither structure nor function. The method of Invention I is distinct from and unrelated to the antibody of Inventions III and IV because the antibody may be neither made by nor used in the method.

Invention I is distinct from and unrelated to inventions V, VIII and IX, wherein the products of Invention I can be neither made by nor used in the method of Inventions V, VIII and IX, and wherein each does not require the other.

The products of Invention I are distinct from and unrelated to the compound of Inventions VI because they are physically and functionally distinct chemical entities which share neither structure nor function.

The nucleic acid of Invention I is related to the method of Invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention I as claimed may be used for the production of the polypeptide of Invention II.

The polypeptide of Invention II is related to the methods of Inventions III, IV, VIII and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II as claimed may be used as a pharmaceutical composition in its own right.

Invention II is distinct from and unrelated to Inventions V and VII, wherein the product of Invention II can be neither made by nor used in the method of Inventions V and VII, and wherein each does not require the other.

The product of Invention II is distinct from and unrelated to the compound of Invention VI because they are physically and functionally distinct chemical entities, which share neither structure nor function.

Although both Inventions III and IV are drawn to an antibody and a method of making, they are distinct because each of the methods has different process steps, different starting and ending points, and requires different active agents, such that they require separate searches.

Inventions III, IV and VII-IX are drawn to independent methods, wherein each of the methods has different process steps, different active agents, different starting and ending points, and is for a different purpose, such that they require separate searches.

Invention VI is distinct from and unrelated to Inventions III, IV and VII-IX, wherein the compound of Invention VI can be neither made by nor used in the method of Inventions III, IV and VII-IX, and wherein each does not require the other.

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121:

A. *One* specific amino acid sequence with SEQ ID NO from the following: SEQ ID NO:3-8, 13-18, 23-28, 33-38, 43, 53-55, 63-65, 73, and 83-85, and

One specific nucleic acid sequence encoding the elected amino acid sequence above with SEQ ID NO from the following: SEQ ID NO:1, 2, 11, 12, 21, 22, 31, 32, 41, 42, 51, 52, 61, 62, 71, 72, 81, or 82

Additionally, **applicants are required** to indicate whether there is a cDNA having a specific ATCC accession number, corresponding to the SEQ ID NO of the elected nucleic acid.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs or ATCC number represents a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I - IX, one from Group A, even though the requirement is traversed. Applicant is advised that neither I - IX nor A are species election requirements; rather, each of I – IX, and A is a restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

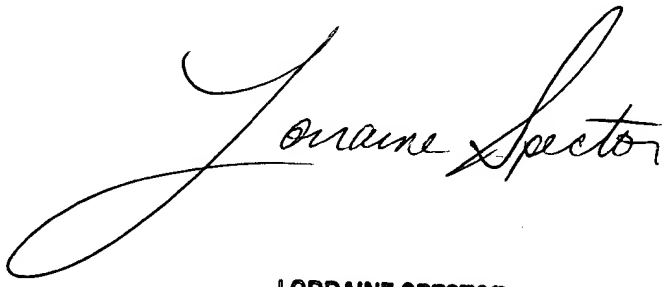
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is (703) 305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703 - 308 - 0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 - 308 - 0196.



LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
9/20/02